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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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T. Ling Chwang
Jackson Walker, L.L.P.
Suite 600
2435 North Central Expressway
Richardson, TX 75080

EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1642	

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/021,741	Mathew et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) *1-13, 36, and 37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *14-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Dec 12, 2001* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Acknowledgment is made of applicants election without traverse of claims 14-35, drawn to a monoclonal antibody and a fusion cell line.

2. Claims 1-37 are pending. Claims 1-13, 36 and 37, drawn to non-elected inventions, are withdrawn from consideration. Claims 14-35 are examined on the merits.

Claim Objections

3. Claim 25 is objected to because of the following informalities: the typographical error of "produce" which should be ---produced---.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 and claim 25 recite "injecting an animal with a synthetic or recombinant proteinaceous molecule or biological equivalent of a natural killer cell surface receptor". It is unclear if the limitation of "a natural killer cell surface receptor" is to be applied to the proteinaceous molecule, or if said limitation is only to be applied to "biological equivalent". For purpose of examination both alternatives will be considered. Further, it is unclear what constitutes a "biological equivalent" of an NK cell surface receptor, therefore the metes and bounds of the claims cannot be determined.

Claims 18, 22, 24, 29, 33 and 35 are rendered vague and indefinite in the recitation of CS1 as the only means to identify the claimed polypeptide. This is a laboratory designation. The use

of laboratory designations only to identify a particular protein/receptor renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct proteins/receptors. Amendment of the claims to include a sequence identifier is recommended.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 14-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to monoclonal antibodies and fusion cells line which are dependent upon the identity of "a synthetic or recombinant proteinaceous molecule" and "a biological equivalent of a natural killer cell surface receptor" in addition to "a sequence homologous to a subset of a CD2 family receptor. The art recognizes that the CD2 family consists of primarily of cell surface receptors that regulate adhesion among different leukocytes and generate-stimulatory signals (see the rejection under 35 U.S.C. 102, as anticipated by Starling et al, below). However, claims 17 and 18 rely specifically upon the sequence identity, not of a CD2 family receptor, but of a sequence homologous to said family of receptors. Thus said claims are drawn to a subfamily of receptors which have not yet been disclosed in the art. It is note that due to the vague and indefinite nature, the claims can be interpreted as being drawn to synthetic or recombinant proteinaceous molecules that are not related to the NK receptor. Also, the specification provides no definition of a biological equivalent NK cell surface receptor. Further, claims 18, 22, 24, 29, 33 and 35 are dependent upon the CS1 receptor. For the reasons stated in

the rejection under 112, second paragraph, above, the meets and bounds of claims drawn to the CS1 receptor are unclear. Consequently, when given the broadest reasonable interpretation, the claims are dependent upon receptors found in other species, mutant receptors, and receptors encoded by neutral alleles. Thus the claims drawn to antibodies and fusion cell lines are dependent upon binding to three genus of proteins: all synthetic or recombinant proteinaceous molecules, an undisclosed sub-family of the CD2 receptors and all potential variants of the CS1 receptor, which was not known in the art at the time of filing. The genuses are variant in structure, and the specification or claims does not provide limitations as to the physical and functional attributes of each genus of proteins so that a protein which is not a member of a claimed genuses can be discerned from proteins which are members. The specification teaches only SEQ ID NO:2 and antibodies which bind thereto, wherein said SEQ ID NO:2 has been termed CS1. This species is insufficient to describe all the members of the claimed genus. One of skill in the art would conclude that applicant was not in possession of the claimed genuses at the time of filing.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent,; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9.The art recognizes that the CD2 family consits of primarily of cell surface receptors that regulate adhesion among diferent leukecytes and generatesco-stimulatory signals. Claims 14-16 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Eda et al (U.S. 6,114,143). Claim 14 is drawn to a monoclonal antibody produced by injecting an animal with a synthetic or recombinant proteinaceous molecule, harvesting spleen cell from said animal, fusing the harvested spleen cells with an immortalized cell line to produce a fusion cell line, screening the fusion cell line to identify cells that specifically produce a monoclonal antibody with affinity toward the synthetic or recombinant proteinaceous molecule. Claim 15 embodies the monoclonal antibody of claim 14 wherein the animal is a mouse. Claim 16 embodies the monoclonal antibody of claim 14 wherein the immortalized cell line comprises a myeloma. Claim 25 is drawn to a fusion cell line produced by injecting an animal with a synthetic or recombinant proteinaceous molecule, harvesting spleen cell from said animal, fusing the harvested spleen cells with an immortalized cell line to produce a fusion cell line, screening the fusion cell line to identify cells that specifically produce a monoclonal antibody with affinity toward the synthetic or recombinant proteinaceous molecule, and selecting a expanding the fusion cell line that specifically produces said monoclonal antibody. It is noted that the metes and bounds of claims 14 and 25 cannot be determined for the reasons set forth in the rejection under 112, second paragraph.

Eda et al disclose a method for making a monoclonal antibody, the monoclonal antibody and fusion cell line made thereby which is the same as that claimed (claim 6 and claim 1).

10. Claims 14-16, 19, 20, 25-27, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Litwin et al (U.S. 5,770,387). Claim 14 is drawn to a monoclonal antibody produced by injecting an animal with a biological equivalent of a natural killer cell surface receptor, harvesting spleen cell from said animal, fusing the harvested spleen cells with an immortalized cell line to produce a fusion cell line, screening the fusion cell line to identify cells that specifically produce a monoclonal antibody with affinity toward the biological equivalent. Claim 15 embodies the monoclonal antibody of claim 14 wherein the animal is a mouse. Claim 16 embodies the monoclonal antibody of claim 14 wherein the immortalized cell line comprises a myeloma. Claim 19 comprises the monoclonal antibody of claim 14, wherein the biological equivalent of the natural killer cell surface receptor comprises a peptide of about 25 to about 50 amino acids residues. Claim 25 is drawn to a fusion cell line produced by injecting an animal with a biological equivalent of a natural killer cell surface receptor, harvesting spleen cell from said animal, fusing the harvested spleen cells with an immortalized cell line to produce a fusion cell line, screening the fusion cell line to identify cells that specifically produce a monoclonal antibody with affinity toward the biological equivalent, and selecting a expanding the fusion cell line that specifically produces said monoclonal antibody. Claim 26 embodies the fusion line of claim 25 wherein the animal is a mouse. Claim 27 embodies the fusion line of claim 25 wherein the immortalized cell line comprises a myeloma. Claim 30 comprises the monoclonal antibody of claim 14, wherein the biological equivalent of the natural killer cell surface receptor comprises a peptide of about 25 to about 50 amino acids residues.

Litwin et al disclose a method for making the monoclonal antibody of DX9 comprising generating immunized mice with human NK clone VL186-1, fusing with spleenocytes with Sp2/0 (column 27, lines 5-10). Litwin et al disclose that the antigen recognized by DX9 is present on a subset of NK cells in adult peripheral blood, therefore VL186-1 is a biological equivalent of a natural killer cell surface receptor. Litwin et al do not specifically disclose the screening of the

fusion cell lines, however, that step would be inherent in the methods disclosed by Litwin et al as the DX9 antibody specifically binds the NKB1 antigen (column 28, lines 20-23)

Further, Litwin et al do not disclose that the biological equivalent of the natural iller cell surface receptor comprises a peptide of about 25 to about 50 amino acid residues, however, it is inherent that the NKB1 antigen comprises a peptide of about 25 to about 50 amino acid residues.

11. Claims 14-21, 23, 24-32, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al (WO 99/63088). The specific embodiments of claims 14-16 and claims 25-27 are set forth above. Claim 17 comprises the monoclonal antibody of claim 14, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor has a predicted peptide sequence homologous to a subset of CD2 receptors. Claim 18 comprises the monoclonal antibody of claim 14, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a CS1 receptor. Claim 19 comprises the monoclonal antibody of claim 14, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a peptide of about 25 to about 50 amino acids residues. Claim 20 comprises the monoclonal antibody of claim 19 wherein the peptide of about 25 to about 50 amino acids is linked to an immunological adjuvant. Claim 21 comprises the monoclonal antibody of claim 14, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a fusion protein. Claim 23 comprises the monoclonal antibody of claim 14, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a peptide of SEQ ID NO:2. Claim 24 comprises the monoclonal antibody of claim 14, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises CS1.

Claim 28 comprises the fusion cell line of claim 25, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor has a predicted

peptide sequence homologous to a subset of CD2 receptors. Claim 29 comprises the fusion cell line of claim 25, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a CS1 receptor. Claim 30 comprises the fusion cell line of claim 25, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a peptide of about 25 to about 50 amino acids residues. Claim 31 comprises the fusion cell line of claim 25, wherein the peptide of about 25 to about 50 amino acids is linked to an immunological adjuvant. Claim 32 comprises the fusion cell line of claim 25, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a fusion protein. Claim 34 comprises the fusion cell line of claim 25, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises a peptide of SEQ ID NO:2. Claim 25 comprises the fusion cell line of claim 25, wherein the synthetic proteinaceous molecule or the biological equivalent of the natural killer cell surface receptor comprises CS1.

Baker et al disclose an antibody made by immunizing an animal with an immunizing agent and adjuvant , wherein the immunizing agent may include the PRO polypeptide of a fusion product thereof. Baker et al disclose the preparation of the antibodies by the monoclonal method which is the same as that claimed (page 365-367). Baker et al disclose a the PRO1138 polypeptide of SEQ ID NO:253 which is identical to the instant SEQ ID NO:2. Thus the antibody disclosed by Baker et al will inherently have the same claimed properties as the instant antibody.

12. Claims 14-35 are rejected under 35 U.S.C. 102(e) and 35 U.S.C. 102(a) as being anticipated by Starling et al (WO 01/46260). The embodiments of claims 14-21, 23-32 and 34-37 are set forth above. Claim 22 embodies the monoclonal antibody of claim 21 wherein the fusion protein comprises CS1-GST. Claim 33 embodies the fusion cell line of claim 32 wherein the fusion protein comprises CS1-GST.

Starling et al disclose antibodies to the extracellular domain of the APEX-1 protein (page 15, lines 25-27 and page 21, lines 7-10) of SEQ ID NO:4 which is identical to the instant SEQ ID NO:2. Starling et al further disclose that APEX-1 is in the CD2 subfamily of extracellular domains which is the specific limitations of claims 17 and 28. Starling et al disclose the preparation of antibodies by APEX-GST fusion proteins and the generation of hybridomas by the method of Kohler and Milstein (page 23, line 24 to page 24, line 2). Thus the monoclonal antibodies and the cell lines producing them will have the same characteristic as the instant claimed antibodies and cell lines.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentable distinct from the reference

claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F. 3d 1428, 46 USPQ2d 1226 (Fed Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

15. Claims 14-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17 ad 18 of copending Application No. 09/475,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the monoclonal antibodies of claims 17 and 18 can anticipate the instant claims 14-16. Claims 14-16 are a product by process, but it appears that the product of the '365 application would have the identical properties to the instant antibodies of claims 14-16.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

March 10, 2003